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Elizabeth A. Dudek
(TYPED OR PRINTED NAME OF PERSON MAILING PAPER OR FEE)

(SIGNATURE OF PERSON MAILING PAPER OR FEE)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:	)
	) Examiner: A. Bhat
Stephen C. Wardlaw, et al.	) Group Art Unit: 2863
	)
Title: APPARATUS FOR PROVIDING QUALITY CONTROL IN AN INSTRUMENT FOR MEDICAL ANALYSIS	)
	)
Serial No.: Unknown	) (Our Docket No. 5169-0011-1-1)
	)
Filed: Herewith	)

Hartford, Connecticut, December 11, 2003

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

S I R:

Applicant(s) submits herewith Form PTO/SB/08A identifying patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Under 37 CFR 1.97 (b)

☑ This Information Disclosure Statement is being filed within three months of the filing date of the application, or the date of entry into the national stage of an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

Under 37 CFR 1.97 (c)

☐ This Information Disclosure Statement is being filed *after* three months of the filing date of this national application, or the date of entry into the national stage as set forth in §1.491 in an international application, or after the mailing date of the first Office Action on the merits, whichever event occurred last, but *before* the mailing date of either a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.

☐ A certification as specified in 37 CFR 1.97(e) is set forth below or
☐ Fee as set forth in 37 CFR 1.17(p) ($180.00).

Under 37 CFR 1.97(d)

☐ This Information Disclosure Statement is being filed *after* a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee. Applicant hereby petitions for the consideration of this Information Disclosure Statement, 37 CFR 1.97(d)(ii). A certification as specified in 37 CFR 1.97(e) is set forth below.

☐ A certification as specified in 37 CFR 1.97(e) is set forth below and

☐ Fee as set forth in 37 CFR 1.17(p) ($180.00).

CERTIFICATION (37 CFR 1.97(e))

☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. A copy of the relevant search report is enclosed herewith.

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing this certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Statement.

Under 37 CFR 1.98(a)(2)(i)

☑ Because the above-referenced application was filed after June 30, 2003, pursuant to USPTO Notice dated 7/11/2003 (*"Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications filed after June 30, 2003"*) Applicant(s) do not provide copies of the U.S. patents identified on the attached PTO/SB/08A form at this time. Should the Examiner require the U.S. patent copies, Applicants respectfully request the Examiner contact Applicants' Representative at the number listed below.

Applicants respectfully request that any deficiencies in the fees be charged to Deposit Order Account No. 13-0235.

Respectfully submitted,

By Richard D. Getz

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Richard D. Getz
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Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	New
Filing Date	HEREWITH
First Named Inventor	STEPHEN C. WARDLAW et al.
Group Art Unit	2863
Examiner Name	A. Bhat
Attorney Docket Number	5169-0011-1-1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,858,154		Anderson, et al.	08/1989	
		2003-0064393		Bass et al.	04/2003	
		6,192,320		Margrey et al.	02/2001	
		2002/0003210		Marcus, R. Kenneth	01/2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Complete if Kn wn	
Application Number	New
Filing Date	Herewith
First Named Inventor	STEPHEN C. WARDLAW. et al
Group Art Unit	2863
Examiner Name	A. Bhat
Attorney Docket Number	5169-0011-1-1

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Information on CLIA Waivers (Clinical Laboratory Improvement Amendments) pages 1-2	
		CLIA Categorization Criteria, pages 1-2	
		CLIA Home Page - Clinical Laboratory Improvement Amendments, pages 1-2	
		Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications pages 1-22	

Examiner Signature		Date Considered	

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